



# Medicines In My Home



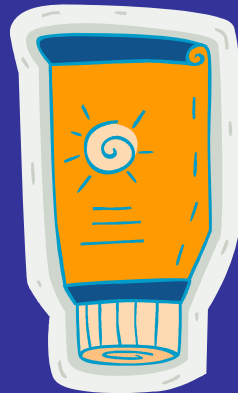
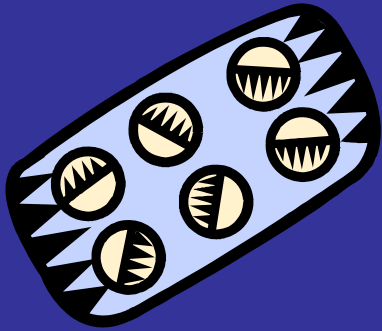
Department of Health and Human Services  
Food and Drug Administration

# Medicines are Drugs

*A medicine or drug...*

- changes how your body works, or
- treats or prevents a disease or symptom

# Who Has Used an Over-the-Counter Medicine This Week?



What are some reasons for using an OTC medicine?



# Prescription and Over-the-Counter Medicines

How are they different?

How are they the same?

# Prescription and Over-the-Counter Medicines

How are they different? How are they the same?

## Prescription

1. Ordered by a doctor
2. Bought at a pharmacy
3. Ordered for and used by only one person

## **Both types of medicine:**

- Directions must be followed carefully and correctly
- Children should use only with permission of a parent or guardian
- A pharmacist can answer questions

## Over-the-Counter

1. Can buy without a doctor's order
2. Bought off the shelf in store aisles
3. May be used by more than one person for the same symptom or problem



How do you decide which medicine is  
the right one for you?

**Read the Drug Facts Label**

## Active Ingredients And what they do

# Drug Facts Label

### Drug Facts

Active ingredients	Purposes
(In each 5 ml teaspoonful) Ibuprofen 100 mg (NSAID)*	Pain reliever/ fever reducer
Phenylephrine HCl 5mg	Nasal decongestant
*nonsteroidal anti-inflammatory drug	

**Uses** temporarily relieves

- nasal and sinus congestion
- stuffy nose
- head ache
- minor body aches and pains
- sore throat
- fever

### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

**Sore throat warning:** Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

### Do not use

- If the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- In a child who is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

### Ask a doctor before use if the child has

- problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

### Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

### Drug Facts (continued)

#### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
- symptoms continue or get worse
- redness or swelling is present in the painful area
- the child gets nervous, dizzy, or sleepless
- any new symptoms appear

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- do not give longer than 10 days, unless directed by a doctor (see Warnings)
- shake well before using
- find right dose on chart below. If possible use weight to dose; otherwise use age.
- use only with enclosed measuring cup
- if needed, repeat dose every 6 hours
- do not use more than 4 times a day
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

Weight (lb)	Age (yrs)	Dose (teaspoonful)
under 24	under 2	ask a doctor
24-47	2 to 5	1 tsp
48-95	6 to 11	2 tsp

### Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration date

**Inactive ingredients** acesulfame potassium, citric acid, corn syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

**Questions?** 1-800-123-4567  
<http://ChildrensFeelBetter.com>

# Active Ingredients:

The parts of the medicine that make it work.

What does **Drug Facts** tell us about each active ingredient ???

- Its **name**
- **How much** is in each pill or teaspoon (5 mL)
- What it does (its **purpose** or job)
- The problems it treats (its **uses**)



# What does this medicine treat?



**Children's  
Feel Better  
Cold and Fever  
Suspension**

★★★★★★★★

**Ibuprofen** ▶ Pain reliever/  
(NSAID) Fever reducer

**Phenylephrine HCL** ▶  
Nasal decongestant

**Relieves:** **Grape Flavor**

**Fever,  
Sore Throat  
Stuffy Nose**



**Drug Facts**

Active ingredients	Purposes
(in each 5 ml teaspoonful) Ibuprofen 100 mg (NSAID)*	Pain reliever/ fever reducer
Phenylephrine HCl 5mg	Nasal decongestant
*nonsteroidal anti-inflammatory drug	

**Uses** temporarily relieves

- nasal and sinus congestion
- stuffy nose
- head ache
- sore throat
- minor body aches and pains
- fever

**Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- rash
- blisters

**Sore throat warning:** Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

**Do not use**

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

# Keisha

- Keisha stayed home from school today because she is sick.
- She has a stuffy nose, sore throat, and aches all over.
- Mom gives her some **Get Better cold and fever medicine** before leaving for work.
- Two hours later, Keisha gets one of her really bad headaches. She wants to take her usual headache medicine to make it go away.



Grape Flavor

# Get Better Cold and Fever Suspension

Relieves:  
**Fever**  
**Stuffy Nose**  
**Minor aches and pains**

**Acetaminophen** ► Pain reliever/  
Fever reducer

**Phenylephrine HCL** ►  
Nasal decongestant

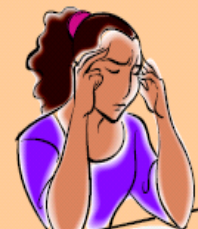
## Drug Facts

Active Ingredients	Purposes
(in each 5 mL teaspoonful) Acetaminophen 500 mg	Pain reliever/ fever reducer
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses** temporarily relieves

- nasal and sinus congestion ■ stuffy nose
- headache ■ sore throat
- minor aches and pains ■ fever

Headache Pain Relief



# Release

Liqui-gel capsules

Relieves:  
**Headache**  
**Fever**  
**Minor aches and pains**

**Acetaminophen** ►  
Pain reliever/Fever reducer

## Drug Facts

Active Ingredients	Purposes
(in each capsule) Acetaminophen 500 mg	Pain reliever/ fever reducer

**Uses** temporarily relieves

- headache ■ sore throat
- minor aches and pains ■ fever

Can Keisha take these  
medicines together?

What's all  
this stuff?

## Drug Facts

### Active ingredients

(In each 5 mL teaspoonful)

Ibuprofen 100 mg (NSAID)\*.....Pain reliever/  
fever reducer

Phenylephrine HCl 5mg.....Nasal decongestant  
\*nonsteroidal anti-inflammatory drug

### Purposes

### Uses

- temporarily relieves
- nasal and sinus congestion
- stuffy nose
- headache
- minor body aches and pains
- sore throat
- fever

### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- rash
- blisters

**Sore throat warning:** Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

### Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- in a child who is taking a monoamine oxidase inhibitor (MAOI) for depression, psychiatric illness, or Parkinson's disease, or the MAOI drug. If you are taking a prescription drug containing a MAOI, ask your doctor or pharmacist before giving this product to your child.

### Ask a doctor before use if the child has

- problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

### Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

## Drug Facts (continued)

### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
- symptoms continue or get worse
- redness or swelling is present in the painful area
- the child gets nervous, dizzy, or sleepless
- any new symptoms appear

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- this product is for oral use. See directions or label for more information.
- unless directed otherwise, use as follows: If possible use the enclosed measuring cup.
- For children 2 to 5 years of age, repeat dose every 6 hours. Do not use more than 4 times a day.
- replace original bottle cap to maintain child resistance
- wash dosage cup after each use

### Dosing Chart

Weight (lb)	Age (yrs)	Dose (teaspoonful)
under 24	under 2	ask a doctor
24-47	2 to 5	1 tsp
48-95	6 to 11	2 tsp

### Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration date

**Inactive ingredients** acesulfame potassium, citric acid, corn syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

### Questions?

1-800-123-4567

<http://ChildrensFeelBetter.com>

Warnings

# Warnings



The warnings section tells you:

- When you **should not** use the medicine at all
- When you should talk to your doctor first
- How the medicine might make you feel
- When you should stop using the medicine
- Things you **should not** do while taking the medicine.





# Allergy Alert

- When your body has an allergic reaction, you may have
  - Itching
  - Rash
  - Hives
  - Swelling
  - Fainting
  - Trouble breathing
- If you think you are allergic to a medicine, do not use it.
- If you think that you or someone else is having an allergic reaction,
  - tell an adult right away.
  - If you or someone else is having trouble breathing or if someone faints, call 911.

Ask a doctor before use...  
Ask a doctor or pharmacist  
before use...



- When to ask a doctor, nurse, or pharmacist BEFORE using the medicine.
  - Some medical problems can make using a medicine less safe.
  - Some medicines should never be used together.



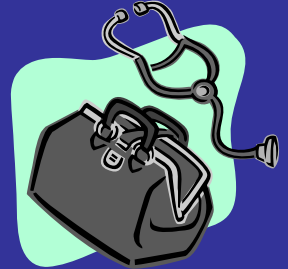
# When using this product...



- Special information about using the medicine.
- Examples...
  - Take with food.
  - Take with liquids.
  - May cause drowsiness (sleepiness).



# Stop use and ask a doctor if...



- Reasons to stop taking a medicine include:

- If you have an allergic reaction
- If you have new problems like stomach pain, throwing up, or dizziness
- If you are not feeling better after a certain number of days



# Keep out of reach of children



- Young children may think medicine tastes **REALLY GOOD**.
- **Medicine is not candy** and can harm them if they take too much.
- If someone you know takes too much medicine or the wrong medicine, tell an adult right away. Call the **Poison Control Center** for help.

# Anthony

- Anthony is 12 years old.
- He is the goalie for his middle school soccer team. Today they play for the county championship.
- Anthony has allergies, and today they are pretty bad. His nose is stuffy and runny and he can't stop sneezing.
- He really wants to feel better before the game. What can he do?



**Chewable Tablets**

**Grape Flavor**

# Feel Better- Allergy Relief

for kids and their grown-ups

Relieves:  
Sneezing,  
Runny nose  
Itchy, watery eyes

Chlorpheniramine ►  
Antihistamine



Because allergies should not  
get in the way

4 Fl Oz (120 mL)



## Drug Facts

### Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg .....Antihistamine

### Purpose

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

### Warnings

**Ask a doctor before use if you have**

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis  
■ trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives

You may get drowsy.

■ avoid alcoholic drinks  
■ tranquilizers may increase drowsiness  
■ do not drive a motor vehicle or operating machinery  
■ excitability may occur, especially in children

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

**Other information** store at 20-25° C (68-77° F) ■ protect from excessive moisture

**Inactive ingredients** D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch



**Chewable Tablets**

**Grape Flavor**

# **Feel Better**

## **Allergy and Congestion Relief**

### **for kids and their grown-ups**

**Relieves:**  
**Sneezing,**  
**Stuffy nose**  
**Itchy, watery eyes**

**Loratadine ►**  
Antihistamine

**Phenylephrine HCL ►**  
Nasal decongestant



**Because allergies should not  
get in the way**

**4 Fl Oz (120 mL)**





# Feel Better: Allergy and Congestion Relief

**Drug Facts**

Active ingredients	Purposes
(In each tablet) Loratadine 5 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of the nasal passages
- temporarily relieves sinus congestion and pressure

**Warnings**

**Do not use**

- If you or the child has ever had an allergic reaction to this product or any of its ingredients and/or another nasal decongestant
- If you or the child is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if you or the child has**

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

**Ask a doctor or pharmacist before use if the child is**

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

Taking more than directed may cause drowsiness.

- an allergic reaction right away.
- symptoms do not improve within 7 days or are accompanied by fever
- nervousness, dizziness, or sleeplessness occurs.

**If pregnant or breastfeeding, ask a health care professional before use.**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

Dosing Chart	
Age (yrs)	Dose (teaspoonful)
under 2	ask a doctor
2 to under 6	Chew one tablet daily, no more than 1 tablet in 24 hours
6 to adult	Chew 2 tablets daily, not more than 2 tablets in 24 hours

**Other information**

- safety sealed. Do not use if blister pack is broken or not labeled
- store at 20-25°C (68-77°F)

**Inactive ingredients** acesulfame potassium, citric acid, corn syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

**Questions?** 1-800-123-4567  
<http://ChildrensFeelBetter.com>



## Drug Facts

Active ingredients	Purposes
(In each 5 ml teaspoonful) ibuprofen 100 mg (NSAID)*	Pain reliever/ fever reducer
Phenylephrine HCl 5mg	Nasal decongestant
*nonsteroidal anti-inflammatory drug	

**Uses** temporarily relieves

- nasal and sinus congestion
- stuffy nose
- head ache
- sore throat
- minor body aches and pains
- fever

## Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

**Sore throat warning:** Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

## Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

## Ask a doctor before use if the child has

- problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

## Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

## Drug Facts (continued)

### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
- symptoms continue or get worse
- redness or swelling is present in the painful area
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- any new symptoms appear

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions For Use**

## Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration date

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**Questions?** 1-800-123-4567

<http://ChildrensFeelBetter.com>

What else do you want to know about your medicine?

How to use the medicine



# Directions



- How much medicine to use
- How often to use it
- How long you can use it

How should you measure your dose of medicine?



# Measuring Tools for Medicines



# Other information and Inactive ingredients



- Other information -
  - How to keep your medicine when you are not using it.
- Inactive ingredients - used to:
  - Form a pill
  - Add flavor or color
  - Make a tablet or film dissolve quickly on your tongue
  - Help a medicine last longer on the shelf





# Questions or Comments

Where to find a telephone number or website to:

- ask questions about the medicine
- report an unexpected reaction to the medicine



# Be Safe!!



Use your OTC medicines wisely

# Take Home Messages

- Speak with a parent or adult before using any medicine.
- Read the label carefully.
  - The information you need to use your OTC medicine safely and correctly is in the Drug Facts Label.
- OTC medicines are serious medicines.
  - Be smart about what you put into your body - it's the only body you have.



We hope you will share this information  
with your family.  
Thank you.



# Additional Resource Slides

